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TITLE: The Breast Health Intervention Evaluation Study

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13c. ABSTRACT (Maximum 200) The Breast Health Intervention Evaluation Study will evaluate the relative effectiveness of three different approaches to breast health messages--a fear appeal, a positive affect appeal, and an affectively neutral cognitive appeal. The three interventions will be structured as three 10-12 minute videotaped presentations targeting 450 African American women residing in three rural communities in Georgia (150/community). Each site will receive one of the three intervention approaches, randomly selected, to be presented within a 60-minute workshop format. Workshops will be coordinated by a Community Lay Health Worker at each site. Pre-/post-intervention KAP surveys will be administered. Participants will be provided with breast self-examination information and breast screening referral information. A 12-month follow-up will be conducted. We will provide referral services to ACR-approved sites for study participants. Analysis and development of the videos will be a collaborative effort between Morehouse School of Medicine and Georgia State University which will also provide expertise in focus group leadership, audience analysis, and lay health worker training. The collaboration of two institutions creates unique strengths that do not currently exist elsewhere in Georgia. Further, working collaboratively will enable us to combine communications theory with public health research practice.			
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FOREWORD

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Daniel S. Blumenthal MD 8/25/99
PI - Signature Date

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Introduction

The Breast Health Intervention Evaluation (BRIE) Study will evaluate the relative effectiveness of three different approaches to breast health messages--a fear appeal, a positive affect appeal, and an affectively neutral, cognitive appeal. The three interventions will be structured as three 10-12 minute videotaped presentations targeting 450 African American women residing in three rural communities in Georgia (150/community). Each site will receive all three of the intervention approaches, and be randomly assigned within the site sample. It will be presented within a 60-minute workshop format. Workshops will be coordinated by a Community Lay Health Worker at each site. Pre-/post-intervention KAP surveys will be administered. Participants will be provided with breast self-examination information and breast screening referral information. A 12-month follow-up will be conducted. We will provide referral services to FDA-approved sites for study participants.

Body: Results & Discussion

This section is organized as follows:

- I. Status of activities reported as unfinished in the Year 02 report
- II. Status of activities relative to the current period (Year 03)
- III. Relevance to the original hypothesis
- IV. Review of the Statement of Work and proposed plans for Year 04

I. Status of Activities Reported as Unfinished in the Year 02 Report

VIDEO PRODUCTION - COMPLETED

As discussed at length in our Year 02 report, we experienced significant delays in the production of the video stimuli for this Study. This activity was originally scheduled for completion by Month 15. We received rough cuts from our collaborative partner, Georgia State University, in Month 24, and final versions in Month 26. As a result of this delay, all subsequent activities relating to the implementation phase of the study were also delayed.

TRAINING OF COMMUNITY LAY HEALTH WORKERS - COMPLETED

Because of the delays in finalizing the videos, we elected to postpone training of the lay health workers until implementation was nearly ready to begin. Otherwise, re-training would have been necessary. The proposed, full-day training has been accomplished as well as an additional half-day update training session following successful completion of the pilot test activities and survey modifications.

PRE-TESTING of MESSAGES - COMPLETED

We conducted an informal pre-test of the rough cuts of the videos among faculty and staffers at Morehouse School of Medicine and Georgia State University. While data from this pre-test was very helpful and encouraging, we felt that a pilot test among groups demographically matched to the

target population should be carried out to ensure that members of the target population will be able to understand the message. (See Pre-Testing of Questionnaire below.)

Based on feedback from the pre-test of the video stimuli, several modifications were carried out. Specifically, the volume of the music soundtrack was decreased, while the spoken components were sharpened and increased slightly in volume to improve clarity. Further, ambient sound was decreased and sound effects were added where appropriate. In terms of the *mise-en-scène*, lighting levels were increased throughout especially in the negatively valenced version. One scene was deleted entirely across all versions--that of a facial grimace from the main character while she is seen having her mammogram. (This portrayal was originally included in response to the focus group observation that mammograms are uncomfortable and that this discomfort should be acknowledged.) Members of pre-test groups, however, were unanimous in stating that this facial reaction was highly dissuasive. Because this issue could not be dealt with within its respective affective context, the scene was deleted entirely throughout.

SURVEY QUESTIONNAIRE ASSESSMENT & MODIFICATIONS - COMPLETED PRE-TESTING OF QUESTIONNAIRE - COMPLETED

We encountered an additional delay when we carried out the pre-testing of the survey instruments. Specifically, we contracted with the Older Americans Council of Middle Georgia in Fort Valley, Georgia in order to recruit an appropriate sample of African American women, aged 45-65, living in rural communities similar to our three target communities, and who had not been diagnosed with breast cancer nor received a mammogram within the preceding 12 months. (The Older American Council of Middle Georgia is an African American community-based organization providing a variety of health services (including home health care, Meals-on-Wheels, etc.) to 13 rural counties. This organization was very helpful in assisting us with the organization of the focus groups in Year 01.) The Older Americans Council arranged for appropriate facilities in which to conduct the pre-test and we provided lunch (in lieu of a cash incentive) for participants. Unfortunately, the recruitment and selection process for this pre-test group was not as rigorous as we had stipulated in that the entire sample of 35 women was between 63-72 years of age. Because of this, we determined that the pre-test was invalid.

Subsequently, a formal pilot test was attempted among 10 participants in each of our target sites; 30 participants in all. A total of 25 persons participated. These participants were recruited by our on-site lay health workers who had already received extensive training regarding subject recruitment and selection. Each site showed only one of the videos randomly assigned.

The pilot test of the workshop was implemented with twenty-five women, ages 45 to 65, with 10, 6, and 9, viewing the videos in the three selected communities. Although these women had been screened prior to participation in the workshop, in their answers to the pre-test survey questions, 4 responded that they had had a mammogram within the past year, and thus were disqualified from the pilot. However, within the group, 52% had a relative or friend who had breast cancer (33.3% a friend, 25% a sister, and 16% a mother).

Most of the pilot test women were aware of the major symptoms of breast cancer (between 40% and 60% for each symptom), based on pre-test survey responses. While nearly half of participants were not aware of the major factors that increase the risk for breast cancer at the pre-test survey, about two-thirds responded correctly to these same questions at the post-test survey.

Following the pilot test, the following changes were made in the pre-/post-survey instruments. The finalized pre/post questionnaire is included as Appendix A. All of these changes were submitted to, and approved by our IRB:

Administration of the Informed Consent

Originally, we had planned to include the informed consent form in each survey set, and to obtain consent from each participant when she attended the workshop. Following our pilot test, the lay health workers revealed that this was a time-consuming, laborious process. In response, we elected to remove the administration of the informed consent from the workshop setting. When subjects are recruited, successfully meet the selection criteria, and are admitted to the Study, they are scheduled for a workshop and provided with a date, time, and location. Prior to their attendance, an informed consent form is mailed to them with instructions to read it carefully, and bring it to the workshop with them. At the beginning of the workshop, questions are answered and signatures are obtained.

Enhanced Confidentiality of Participant Data

By removing the informed consent from the survey set, and by coding the survey sets, we are able to enhance confidentiality of survey data. Further, by using the Participant Contact Form (Appendix B) that includes the survey codes, we are able to link a specific survey with the respondent's consent form. The Participant Consent Form will also serve as the source of contact information for the telephone follow-up.

Deletion of Breast Self-Examination Items from the Survey Instruments

Our pre-/post-survey instruments are modified versions of the 24-item Breast Cancer Awareness Survey developed by the National Black Leadership Initiative on Cancer. The Breast Cancer Awareness Survey included 3 items dealing with breast self-examination. We elected to delete these items from the final instruments in the interest of reducing the length of the survey, and because BSE is not part of the research protocol of this Study. The provision of BSE information is part of the workshop protocol from an educational, not investigative, perspective.

Changes in Likert Scale Items

Originally, we elected to provide a 7-level Likert Scale regarding breast health and breast cancer knowledge and attitudes, and with respect to the participants' appraisal of the video stimulus. This range of response choices proved to be difficult and confusing for respondents. Therefore, we decreased the range of response choices to 5.

RECRUIT STUDY PARTICIPANTS - IN PROGRESS

The delays that we encountered in the initial developmental phase with respect to both the video production and the questionnaire pre-testing adversely impacted implementation phase including both participant recruitment as well as workshop scheduling and conduct (discussed in subsection III. following).

In terms of subject recruitment protocol, however, we developed a Participant Contact Form (Appendix B) to serve the following functions:

- a. To provide a means of tracking the productivity of lay health workers
- b. To enable the lay health workers to centralize important contact information
- c. To provide a checklist to enable lay health workers to establish participant eligibility
- d. To provide a coding mechanism, thus enhancing confidentiality
- e. To provide centralized contact information for the telephone follow-up activities
- f. To enable verification of eligibility criteria by Study Team members.

The entire Study sample was specified at 450 participants (150 in each of three communities). Based on expected losses during period before telephone follow-up, we will increase the sample by approximately 25 participants in each location. To date, we have recruited 102 subjects into the Study. Of these, 89 are scheduled to attend a workshop, or have completed the workshop protocol.

II. Status of Activities Relative to the Current Period (Year 03)

According to the Statement of Work, Months 25-36 (Year 03) involved the following activities:

Month	
21 - 27	Organize and conduct 5-7 workshops in each target community
28 - 29	Evaluate data gathered in workshops
30 - 31	Recruit & train graduate student phone interviewers
32 - 34	Implement 12-month follow-up
35 - 36	Analyze data and write reports

ORGANIZE and CONDUCT 5-7 WORKSHOPS in EACH TARGET COMMUNITY

Because of developmental delays, we have had to compress the implementation phase in order to complete the study within the time allotted including the approved 12-month extension. This revision of the timeline has been communicated to the lay health workers in each site, and they are strengthening their recruitment efforts by seeking referrals from workshop participants of other women in their respective communities who may be interested in participating in this Study. The selection criteria, however, have not been relaxed, and referral is not necessarily synonymous with admission.

Additionally, in our half-day training update session, the issue of workshop size was revisited. While smaller groups (of approximately 10-15) may have been optimal, this group size is no longer practicable. Larger groups (of approximately 20-25) increase the labor required of the lay health workers and in order to compensate for this, we have reconfigured the administration of the informed consent process and deleted extraneous items from the surveys. Both of these modifications are discussed above.

**EVALUATE DATA GATHERED in WORKSHOPS
RECRUIT & TRAIN GRADUATE STUDENT PHONE INTERVIEWERS
IMPLEMENT 12-MONTH FOLLOW-UP
ANALYZE DATA and WRITE REPORTS**

These activities will be carried out in Year 04 (the approved 12-month extension). See IV. below.

III. Relevance to the Original Hypothesis

Because of the implementational delays as discussed briefly above (and in depth in our Year 02 report), our dataset is unanalyzable at the current time. Data entry is being carried out concurrently with data collection, however, no interim analyses are planned due to statistical compromise.

The pilot test was not intended for hypothesis testing, but to assure that the protocol under which the workshops would be implemented was adequate. However, as all aspects of the protocol were utilized, data were collected from which preliminary impressions can be drawn. This format appears to be appropriate for increasing the knowledge of participants as to the need for and use of mammography as well as the major risk factors for breast cancer. Additionally, we added a Risk Score to both the pre- and post- test surveys and women viewing different videos had quite different changes in their perceptions of personal risk for breast cancer between the pre- and post surveys. It is plausible that women viewing a single video could not articulate the affective content, due to its almost subliminal impact, although overall responses to explicit questions varies with affective content. This, of course, is the primary hypothesis to be tested at the end of the implementation and analysis phase of this study.

IV. Review of the Statement of Work and Proposed Plans for Year 04

COMPLETED	Focus Groups
COMPLETED	Videoscript development
COMPLETED	Videoscript process evaluation
COMPLETED	Videoscript assessment
COMPLETED	Pre-testing of messages
COMPLETED	Lay Health Worker Training Curriculum Development
COMPLETED	Develop Procedures Manual
COMPLETED	Recruit, hire, & train Community Lay Health Worker in each site
COMPLETED	Survey Q'aire Assessment & Modifications
COMPLETED	Pre-testing of Q'aire
COMPLETED	Video Production
COMPLETED	Establish relationships with target communities
COMPLETED	Assess sociodemographics and comparability of communities
IN PROGRESS	Recruit study participants

COMPLETED	Identify mammography and clinical breast exam sites
IN PROGRESS	Organize and conduct 5-7 workshops in each target community
YEAR 04	Evaluate data gathered in workshops
YEAR 04	Recruit & train graduate student phone interviewers
YEAR 04	Implement 12-month follow-up
YEAR 04	Analyze data and write reports

PLANS FOR YEAR 04 (Months 37 - 48)

As discussed elsewhere in this, and in our Year 02 reports, two significant delays impacted the implementational timeline of this Study: (1) delays in the production of the video stimuli, and (2) invalidation of a survey pre-test group. Because of this, we requested and received a 12-month, no cost extension of this Study (Year 04).

Recruitment of study participants and the conduct of the workshops are currently in progress. Data from completed surveys will be evaluated for conformance with eligibility criteria and will be entered into EpiInfo 6, our data analysis application, upon receipt. We anticipate that this activity will be completed by Month 39.

In order to complete the Study by Month 48, we are currently considering reducing the initiation of the follow-up protocol from 12 months to 10 or 8 months. We do not feel that this change will compromise the testing of our Study hypotheses because participants will be exposed to the videotaped stimulus for one time only. Message reinforcement and retention are not variables under investigation in this Study. Therefore, we hypothesize that maximum compliance with the message recommendations (i.e., to get a clinical breast exam and to get a mammogram) is most likely to occur very shortly after exposure to the stimulus (within 1-2 months), and recall of the message and retention of the recommendation will erode continually thereafter. Therefore, detection of any differences in recommendation compliance among different affective valences should not be affected by a shortened follow-up interval.

Recruitment of student phone interviewers could not proceed until the beginning of the fall semester when students return for classes and are able to respond to recruitment efforts. Formulation of recruitment efforts is currently underway in terms of ascertaining graduate student availability and interest. We anticipate that recruitment will be finalized toward the end of the fall semester (Month 39), and that the telephone follow-up activities will begin during the spring semester Months 45 or 46.

Finally, we project that data analysis and report preparation will occur in Months 47 and 48.

Key Research Accomplishments

- ◆ Production of three, affectively different videotaped stimuli that were developed based on data collected through extensive focus group sessions involving women in the target population.
- ◆ Development and testing of pre-/post survey questionnaires.
- ◆ Development of training manual and protocol for lay health workers to utilize during the implementation of research in predominantly African American rural communities.

Reportable Outcomes

None

Conclusions

As with most collaborative research studies, unforeseen events occur that are beyond the control of the researchers, and this has been true with regard to the Breast Health Intervention Evaluation Study. However, from a broad perspective, our setbacks have been limited to video production issues and to the survey pre-testing protocol, both of which have been dealt with satisfactorily. The pace of the implementation activities, currently in progress, has been increased, and we are currently considering reduction of the follow-up interval. Therefore, we foresee no further difficulties in fully completing the Study by 31 July 2000.

References

None

Appendix

- | | |
|------------|--------------------------|
| Appendix A | Pre-/Post Survey Set |
| Appendix B | Participant Contact Form |

APPENDIX A

ID NUMBER _____

LOCATION _____

DATE _____

A

B

C

THE BRIE STUDY SURVEY SET

FIRST SURVEY

Please fill in the blank or check the correct response. If your reponse includes a direction (Go to Question X), DO NOT answer the questions in between.

1. What is your age? _____
2. What was your household income last year?
 1 Less than \$10,000
 2 \$10,000 - \$14,999
 3 \$15,000 - \$24,999
 4 \$25,000 - \$34,999
 5 \$35,000 - \$49,999
 6 \$50,000 or more
 0 Unknown
3. What level of education have you completed?
 1 Less than high school graduate
 2 High school graduate or GED
 3 Some college or technical school
 4 College graduate
 5 Advanced college degree
 6 Other
4. What is your marital status?
 M Married
 S Single
 D Divorced, widowed, or separated
5. Do you have a regular source of health care?
 Y Yes
 N No
6. How do you pay for your health care? (Check all that apply)
 Y Private Insurance
 Y Medicaid
 Y Medicare
 Y Cash, check, money order, or credit card
 Y Other
7. Has any one in your family or any close friend been diagnosed with breast cancer?
 Y Yes
 N No (Go to Question 9.)
 D I don't know (Go to Question 9)

8. If yes, what is the relationship to you? (Check all that apply.)

- M Mother
- S Sister
- D Daughter
- F Close Friend
- O Other Relative

9. Have you ever been diagnosed with breast cancer?

- Y Yes
- N No

10. Have you ever smoked or used tobacco?

- C Yes, I smoke or use tobacco now.
- F Yes, I used to smoke or use tobacco in the past.
- N No, I have never regularly smoked or used tobacco.

11. What do you think are some of the warning signs or symptoms of breast cancer? (Check all that apply.)

- Y Lumps in the breast
- Y Shortness of breath
- Y Pain, soreness, burning in the breast
- Y Nausea
- Y Discharge from the nipple
- Y Swelling or enlargement of the breast
- Y Changes in shape of breast or nipple
- Y Discoloration

12. Have you ever heard of a mammogram?

- Y Yes
- N No

13. Have you ever had a mammogram?

- 1 Yes, within the past 12 months (Go to Question 15)
- 2 Yes, between 1-2 years ago (Go to Question 15)
- 3 Yes, between 2-3 years ago
- 4 Yes, more than 3 years ago
- 0 No, I have never had a mammogram.

14. If you have not gotten a mammogram regularly, why? (Check all that apply.)

- Y I don't know how or where to get one.
- Y I don't believe that it increases my chances of survival.
- Y I don't believe that I am at risk for breast cancer.
- Y I'm afraid.
- Y I can't afford it.
- Y I've never been told to get a mammogram.

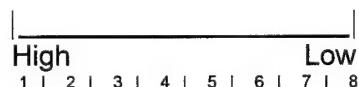
Please circle the response that indicates whether you think the following statements are TRUE or FALSE.

- | | |
|--|-------|
| 15. Mammograms are not very effective at detecting breast cancer. | T F |
| 16. Breast cancer is more difficult to cure if detected early. | T F |
| 17. Mammograms can cause breast cancer. | T F |
| 18. Women who do monthly breast self-examination are more likely to find a lump that could indicate a problem. | T F |
| 19. Women with a family member who has had breast cancer are at <u>greater</u> risk for breast cancer than women without such a family history. | T F |
| 20. Women who are overweight are at <u>greater</u> risk for breast cancer than women who aren't. | T F |
| 21. Women who do not smoke are at <u>less</u> risk for breast cancer than women who smoke. | T F |
| 22. Women who are older than 50 are at <u>greater</u> risk for breast cancer than women who are younger than 50. | T F |
| 23. African American women in general are at <u>lower</u> risk for dying from breast cancer than are women of other races. | T F |

Please circle the response that most closely indicates your agreement or disagreement with the following statements

		Strongly Agree	Mostly Agree	Neither Agree nor Disagree	Mostly Disagree	Strongly Disagree
24.	I am responsible for taking care of my own body including my breasts.	1	2	3	4	5
25.	Mammograms can hurt.	1	2	3	4	5
26.	There is nothing I can do to prevent breast cancer.	1	2	3	4	5
27.	I don't like to touch my own breasts for breast self-examination.	1	2	3	4	5
28.	I need to get a mammogram every one to two years.	1	2	3	4	5
29.	Breast cancer is the will of the Lord.	1	2	3	4	5
30.	I would be more likely to get a mammogram if encouraged or supported by someone close to me (husband, best friend, sister, etc.).	1	2	3	4	5
31.	I think mammograms are worth it.	1	2	3	4	5
32.	I don't want to get a mammogram because I'm afraid of what it might show.	1	2	3	4	5
33.	Getting a mammogram is embarrassing.	1	2	3	4	5
34.	I am not afraid of getting a mammogram.	1	2	3	4	5

This line represents breast cancer risk. Mark (I) on the line where you believe YOUR risk of getting breast cancer is.



STOP

**DO NOT TURN THE PAGE UNTIL
YOU ARE TOLD TO DO SO**

SECOND SURVEY

Directions: Circle the number of the response that MOST ACCURATELY describes your feelings.

		Very negative	Mostly negative	Neither negative nor positive	Mostly positive	Very positive
1.	How did the video make you <u>feel</u> about the importance of screening and early detection of breast cancer?	1	2	3	4	5
2.	How did the video make you <u>feel</u> about getting a mammogram?	1	2	3	4	5
3.	Overall, how did you <u>feel</u> about the characters?	1	2	3	4	5
4.	How did you <u>feel</u> about what they said to one another?	1	2	3	4	5
5.	How did you <u>feel</u> about the way they talked/acted toward one another?	1	2	3	4	5
6.	How did you <u>feel</u> about the story?	1	2	3	4	5
7.	How did you <u>feel</u> about the scenery?	1	2	3	4	5
8.	How did you <u>feel</u> about the music?	1	2	3	4	5
9.	How would you rate the overall tone of the video?	1	2	3	4	5
10.	Which character did you like the most ?					
	Ruby	Mary	Frank (Husband)	Dr. Lee		
11.	Which character did you like the least ?					
	Ruby	Mary	Frank (Husband)	Dr. Lee		
12.	What do you think Ruby's mammogram results are?					
	<input type="checkbox"/> P	Positive (There might be a problem.)				
	<input type="checkbox"/> N	Negative (She's fine.)				
	<input type="checkbox"/> D	I don't know				

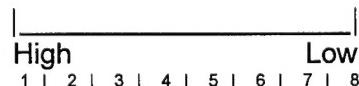
Please circle the response that indicates whether you think the following statements are TRUE or FALSE.

- | | |
|---|-------|
| 13. Mammograms are not usually effective at diagnosing breast cancer. | T F |
| 14. Breast cancer is more difficult to cure if detected early. | T F |
| 15. Mammograms can cause breast cancer. | T F |
| 16. Women who do monthly breast self-examination are more likely to find a lump that could indicate a problem. | T F |
| 17. Women with a family member who has had breast cancer are at <u>greater</u> risk for breast cancer than women without such a family history. | T F |
| 18. Women who are overweight are at <u>greater</u> risk for breast cancer than women who aren't. | T F |
| 19. Women who do not smoke are at <u>less</u> risk for breast cancer than women who smoke. | T F |
| 20. Women who are older than 50 are at <u>greater</u> risk for breast cancer than women who are younger than 50. | T F |
| 21. African American women in general are at <u>lower</u> risk for dying from breast cancer than are women of other races. | T F |

Please circle the response that most closely indicates your agreement or disagreement with the following statements

	Strongly Agree	Mostly Agree	Neither Agree nor Disagree	Mostly Disagree	Strongly Disagree
22. I am responsible for taking care of my own body including my breasts.	1	2	3	4	5
23. Mammograms can hurt.	1	2	3	4	5
24. There is nothing I can do to prevent breast cancer.	1	2	3	4	5
25. I don't like to touch my own breasts for breast self-examination.	1	2	3	4	5
26. I need to get a mammogram every one to two years.	1	2	3	4	5
27. Breast cancer is the will of the Lord.	1	2	3	4	5
28. I would be more likely to get a mammogram if encouraged or supported by someone close to me (husband, best friend, sister, etc.).	1	2	3	4	5
29. I think mammograms are worth it.	1	2	3	4	5
30. I don't want to get a mammogram because I'm afraid of what it might show.	1	2	3	4	5
31. Getting a mammogram is embarrassing.	1	2	3	4	5
32. I am not afraid of getting a mammogram.	1	2	3	4	5

This line represents breast cancer risk. Mark (I) on the line where you believe YOUR risk of getting breast cancer is.



CONTACT FORM

Name _____ Phone _____ Alt. Phone _____

Address _____ City _____, GA Zip _____

ELIGIBILITY GUIDELINES

African American female aged 45-65? Y N NOT ELIGIBLE

Ever had a mammogram? Y N

If yes, about how many months/years ago? _____ WKSHP DATE _____ TIME _____

History of breast cancer? Y N

History of breast surgery? Y N

No show Reschl'd for _____Attended ID Number _____

INFORMED CONSENT SIGNED? Y N

Name _____ Phone _____ Alt. Phone _____

Address _____ City _____, GA Zip _____

ELIGIBILITY GUIDELINES

African American female aged 45-65? Y N NOT ELIGIBLE

Ever had a mammogram? Y N

If yes, about how many months/years ago? _____ WKSHP DATE _____ TIME _____

History of breast cancer? Y N

History of breast surgery? Y N

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